DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

OCtober 14, 2014

Navilyst Medical, Incorporated
Ms. Wanda Carpinella
Director Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K142616
Trade/Device Name: PICC Maximal Barrier Nursing Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter.
Regulatory Class: II
Product Code: LJS
Dated: September 15, 2014
Received: September 16, 2014

Dear Ms. Carpinella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142616

Device Name
PICC Maximal Sterile Barrier with NMI PICC III (BioFlo Hybrid PICC with Endexo Technology)

Indications for Use *(Describe)*
The NMI PICC III is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI PICC III is 6 mL/sec.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142616

Device Name
PICC Maximal Barrier Nursing Kit with NMI PICC III (BioFlo PICC with Endexo Technology)

Indications for Use *(Describe)*

NON-VALVED VERSION
The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.
Maximum Power Injection Flow Rate:
- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 cm 6 mL/sec

VALVED VERSION
The NMI PICC III with PASV Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.
Maximum Power Injection Flow Rate:
- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 cm 6 mL/sec

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142616

Device Name
PICC Maximal Barrier Nursing Kit with Xcela® Hybrid PICC with PASV® Valve Technology

Indications for Use *(Describe)*

The Xcela Hybrid PICC with PASV Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142616

Device Name
PICC Maximal Barrier Nursing Kit with NMI PICC II (Xcela PICC with PASV Valve Technology, 3F SL and 6F TL)
PICC Maximal Barrier Nursing Kit with NMI PICC II (Xcela PICC with PASV Valve Technology,4F SL through 6F DL)
PICC Maximal Barrier Nursing Kit with BSC PICC (Xcela Power Injectable PICC)

Indications for Use *(Describe)*

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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26 Forest Street
Marlborough, MA 01752
Tel 508.658.7990

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K142616

510(k) Summary for the PICC Maximal Barrier Nursing Kit

Date prepared: 11 September 2014

A. Submitter/Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Wanda Carpinella
Director Regulatory Affairs
Phone: 508-658-7979

or

Gary Barrett
Director Regulatory Affairs
Phone: 508-658-7940

C. Device Name

Trade Name:	PICC Maximal Barrier Nursing Kits
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21 CFR §880.5970, Class II, Product Code LJS
Classification Panel:	General Hospital Device Panel

D. Predicate Device

Trade Name:	PICC Maximal Barrier Nursing Kits
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21 CFR §880.5970, Class II
Classification Panel:	General Hospital Device Panel
Premarket Notification	K131038

E. Device Description

The PICC Maximal Barrier Nursing Kit is a packaging configuration containing a specified NMI PICC, along with (1) procedural aides typically used for PICC placement and (2) *maximal barrier precaution* devices based upon recommendations of Center of Disease Control and Prevention (CDC).

The associated accessories include:

Sterile Kit:

- Ampule Breaker
- Cannula 1 ¾" Filtered Straw
- Cap, male, non-vented
- Cover, Transducer, 4" x 58"
- CSR Wrap
- Dilator/Sheath, 3-6F x 5 or 7 cm peelable, (sized to PICC)
- Drape, Full Body
- Drape, Under arm
- Drape, Fenestrated
- Dressing, Tegaderm
- Chloraprep 3mL clear and orange tint
- Gauze 4" x 4", 4 ply
- Gown, Surgical Extra Large
- Guidewire, 0.18" x 45 cm
- Hairnet, 24" large
- Lidocaine ampule
- Mask with earloops
- Needle, echogenic 21G x 1.575" or 2.75" (sized to PICC)
- Needle, 25G x 5/8"
- Needle, safety 21 G x 2.75"
- PICC (based on family and size)
- Scalpel, #11, Safety
- Scissors, Blunt
- Sharps container, single
- Skin Protectant Swab Stick
- Statlock Plus Fixed Post (stabilization)
- Stiffening Stylet 0.014" or 0.016" x 70 cm (size to PICC)
- Syringe 5cc
- Tape Measure, 36" Paper
- Tape, Surgical 3/4" x 24"
- Tourniquet, 18" x 1"
- Towel, 14" x 25"
- Tuohy Borst Adapter w/side arm

Tandem Package (Pouch): Sterile OEM Devices in 'as received' packaging

- Gloves, Surgeons
- Pre-Filled Syringes, Saline

F. Indications For Use

- PICC Maxi mal Sterile Barrier Kit with NMI HPICC III (BioFlo Hybrid PICC with Endexo Technology)

The NMI HPICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

- PICC Maximal Sterile Barrier Kit with NMI PICC III (BioFlo PICC with Endexo Technology)

NON-VALVED VERSION

The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 – 6 mL/sec

VALVED VERSION

The NMI PICC III with PASV Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 – 6 mL/sec

- PICC Maximal Sterile Barrier Kit with Xcela® Hybrid PICC with PASV® Valve Technology:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec.

- PICC Maximal Barrier Nursing Kit with NMI PICC II (Xcela PICC with PASV Valve Technology, 3 Fr single lumen and 6 Fr triple lumen)

  Or

  PICC Maximal Barrier Nursing Kit with NMI PICC (Xcela PICC with PASV Valve Technology, 4 Fr single lumen through 6 Fr double lumen)

  Or

  PICC Maximal Barrier Nursing Kit with BSC PICC (Xcela Power Injectable PICC)

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

G. Comparison of Technological Characteristics With the Predicate Device

Similarities
The proposed PICC Maximal Barrier Nursing Kit contains a PICC catheter packaged with a variety of procedural aide componentry typically used during PICC placement. The proposed PICC indications for use, technological characteristics, materials and operating principles are identical.

Differences
The proposed PICC Maximal Barrier Nursing Kit has a new outer tray lid and adhesive as compared to the predicate PICC Maximal Barrier Nursing Kit packaging.

H. Performance Data

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. The performance evaluation of the PICC Maximal Barrier Nursing Kit new outer tray lid and adhesive was conducte in accordance with the following national/international standards:

- AAMI/ANSI/ISO 11607-1 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* (2006)
- AAMI/ANSI/ISO 11607-2 *Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes* (2006)

I. Conclusion

Based on results of package testing performed according to recognized standards, the proposed PICC Maximal Barrier Nursing Kit is determined to be substantially equivalent to the predicate PICC Maximal Barrier Nursing Kit.